REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of Claims

After entry of the amendments, claims 3, 4 and 6-12 will be pending in the present application. Claims 1, 2 and 5 were previously canceled. Claims 3 and 4 have been amended without prejudice or disclaimer of the subject matter contained therein. New claims 6-12 have been added. Support for amended claims 3 and 4 and new claims 6-12 can be found at least at page 2, lines 3-7; page 3, lines 1-9; page 4, lines 5-9; and page 5, lines 11-18 of the specification.

Based upon the considerations above, entry of the present Amendment is respectfully requested.

In view of the following remarks the Examiner is respectfully requested to withdraw the outstanding rejections and allow the pending claims.

Issues under 35 U.S.C. § 102(b)

Claims 3 and 4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hung, US 2002/0045260 (hereinafter "Hung") in light of Whittle *et al.*, "*The Characterization of Human Amnion Epithelial and Mesenchymal Cells: the Cellular Expression, Activity and Glucocorticoid Regulation of Prostaglandin Output*," Placenta Vol. 21, pp. 394-401, (2000) (hereinafter "Whittle"). Applicants respectfully traverse this rejection.

One skilled in the art would know that a wide array of stem cells exist, each having unique capabilities to self-renew, grow indefinitely, and differentiate and develop into multiple types of cells and tissues. Stems cells are rare in the tissues, and on a microscopic level they look just like the other cells in the tissue where they are found. Different types of stem cells will have different stem cell markers/stem cell receptors.

There is no test that can be performed on a single cell to determine whether that cell is a mesenchymal stem cell. There are surface antigens that can be used to isolate a population of

cells that have similar self-renewal and differentiation capacities. Mesenchymal stem cells, as a population, typically do not all express the same markers.

While Hung discloses that sources of mesenchymal stem cells include "bone marrow, embryonic yolk sac, placenta, umbilical cord, and fetal, adolescent and adult body fluids and tissues," Hung is silent as to amnion being a source of bone stem cells and, more specifically, to collecting bone stem cells only from the mesenchymal layer of human amnion. One skilled in the art would recognize that the placenta contains tissues other than amnion. The proportion of bone stem cells found in a mixture of cells collected from the entire placenta would be smaller than the proportion found in a mixture of cells collected from only the mesenchymal layer of the amnion, as in the claimed invention. In order to collect cells only from the mesenchymal layer of the amnion, the amnion must be separated from other parts of the placenta (such as the chorion), and the amniotic epithelial cell layer must be separated from the amniotic cell layer. Hung does not teach these steps. Hung also does not teach that mesenchymal stem cells obtained from placental tissues other than the amniotic mesenchymal layer are the same as the bone stem cells collected from the mesenchymal layer of the amnion, as in the claimed invention.

The working examples taught by Hung rely on mesenchymal stem cells derived only from bone marrow, and therefore, the bone cells produced in Hung's examples are derivatives of bone marrow mesenchymal stem cells. Hung does not teach which of the listed tissue sources, other than bone marrow, yield bone stem cells.

Again, Hung is silent as to producing bone cells from bone stem cells that are collected from human amniotic mesenchymal cell layer. Furthermore, Whittle is silent as to stem cells being present in the mesenchymal layer of the amnion, and more specifically, Whittle is silent as to bone stem cells in the amnion. Whittle merely characterizes prostaglandin output of a mixture of cells from the mesenchymal layer of the amnion, and very few, if any, of these cells would be bone stem cells.

Hung and Whittle taken alone or together do not teach collecting bone stem cells from a human amniotic mesenchymal cell layer, as in the claimed invention. In view of the amendments to the claims, and the discussion above, Applicants respectfully request withdrawal

of the rejection of claims 3 and 4 under 35 U.S.C. § 102(b) as being anticipated by Hung in light of Whittle.

With regard to new claims 6-9, 11 and 12, Hung and Whittle do not teach stem cells expressing an SB-10 antigen (a stem cell marker) as in the claimed invention. Also, Hung specifically teaches away from isolating stem cells using antigens as in claims 6-9, 11 and 12. (*See* the "Abstract" and "Background" sections of Hung.) With regard to new claim 10, Hung and Whittle taken alone or together do not teach collecting cells from a mesenchymal cell layer of human amnion, and transplanting the collected cells into a bone defect, wherein the collected cells comprise stem cells and other amniotic cell types.

CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Stephanie A. Wardwell, Reg. No. 48,025, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated:

NOV 02 2009

Respectfully submitted,

By #43575
Craig A. McRobbie for
Registration No.: 42,874
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant

SAW
CAM/SAW:kml